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5. 510(k) SUMMARY of the XT-Series- IG and RET-He parameters

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
The assigned 510(k) number is: K081890.

1. Submitted by:	Sysmex America, Inc. One Nelson C. White Parkway Mundelein, IL 60060 Phone: (847) 996-4682; FAX: (847) 996-4655 Contact person: Carrie S. Pineda Date prepared: July 2, 2008
2. Name of Device:	Trade or proprietary name: RET-He parameter on Sysmex® XT-Series IG parameter on Sysmex® XT- Series Common name: Automated Hematology Analyzer Classification name: Sysmex® XT- Series, Automated Hematology Analyzer, an Automated Differential Cell Counter, (21 CFR 864.5220) is a Class II device.
3. Predicate Method:	RET-He parameter on Sysmex® XE-2100 (K050589-Cleared May 5, 2005) IG parameter on Sysmex® XE-2100 (K032039-Cleared Sept 8, 2003)
4. Device Description:	The XT-Series is an automated hematology analyzer previously cleared by the FDA (K021241- cleared June 24, 2002). The RET-He parameter determines the hemoglobin of reticulocytes. XT-Pro and RET- Master are required. The IG parameter (Immature Granulocyte) classifies and counts the immature granulocyte cells. The XT-Pro and IG Master are required.
5. Intended Use:	The IG parameter on the Sysmex® XT-Series, Automated Hematology Analyzer, is intended for *in vitro* diagnostic use to classify and count immature granulocyte cells in EDTA anti-coagulated blood. The RET-He parameter on the Sysmex® XT-Series, Automated Hematology Analyzer, determines the hemoglobin of reticulocytes for *in vitro* diagnostic use in EDTA anti-coagulated blood. IG% / # Immature Granulocyte Percent and Count RET-He Reticulocyte Hemoglobin
6. Substantial equivalence- Similarities and Differences:	Table 1 shows substantial equivalence of the XT-Series to the XE-2100.
7. Conclusion	The XT-Series IG and RET-He parameters demonstrate substantial equivalence to the XE-2100 IG and RET-He parameters.

Table 1: Substantial Equivalence—Similarities and Difference to XE-2100

	Sysmex XE-2100- IG and RET-He parameters	**Sysmex XT-Series- IG and RET-He parameters**	
	Predicate	**New parameters**	**Similarity/ Difference**
Intended Use	IG Parameter: The IG parameter on Sysmex® XE-2100 is intended for *in vitro* diagnostic use to classify and count immature granulocyte cells in EDTA anti-coagulated blood. RET-He Parameter: The RET-He parameter on the Sysmex® XE-2100, Automated Hematology Analyzer, determines the hemoglobin of reticulocytes for *in vitro* diagnostic use in clinical laboratories.	IG Parameter: The IG parameter on Sysmex® XT-Series is intended for *in vitro* diagnostic use to classify and count immature granulocyte cells in EDTA anti-coagulated blood. RET-He Parameter: The RET-He parameter on the Sysmex® XT-Series, Automated Hematology Analyzer, determines the hemoglobin of reticulocytes for *in vitro* diagnostic use in clinical laboratories.	Both systems have the same intended use statement.
Methodology	IG Parameter: The Immature Granulocyte (IG) count is measured in the DIFF channel. The combination of side scatter, forward scatter, and fluorescent intensity of nucleated cells give an image of each cell detected in the peripheral blood. Different leukocyte populations or clusters such as the immature granulocytes are counted. RET-He Parameter: The reticulocyte parameters are derived using the reticulocyte forward scattered light signals from the reticulocyte measurement channel and a proprietary Sysmex calculation equation.	IG Parameter: The Immature Granulocyte (IG) count is measured in the DIFF channel. The combination of side scatter, forward scatter, and fluorescent intensity of nucleated cells give an image of each cell detected in the peripheral blood. Different leukocyte populations or clusters such as the immature granulocytes are counted. RET-He Parameter: The reticulocyte parameters are derived using the reticulocyte forward scattered light signals from the reticulocyte measurement channel and a proprietary Sysmex calculation equation.	Both systems use the same methodology.
Reagents	CELLPACK™ (Diluent) CELLSHEATH™ (Diluent) STROMATOLYSER-FB™ (Lyse) STROMATOLYSER-4DL™ (Lyse) STROMATOLYSER-4DS™ (Stain) STROMATOLYSER-NR™	CELLPACK™ (Diluent) STROMATOLYSER-FB™ (Lyse) STROMATOLYSER-4DL™ (Lyse) STROMATOLYSER-4DS™ (Stain) SULFOLYSER (Lyse) RET-SEARCH II (Diluent)	The XT-Series uses less reagents due to the fact that it doesn't test for NRBC#/%.

	(Diluent) STROMATOLYSER-NR™ (Stain) STROMATOLYSER-IM™ (Lyse) SULFOLYSER (Lyse) RET-SEARCH II (Diluent) RET-SEARCH II (Stain)	RET-SEARCH II (Stain)	
Quality Control/ Calibrator	*e*-Check—3 levels X Cal	*e* -Check —3 levels X Cal	The XE-2100 and the XT-Series use the same Calibrator and control material.
Software/ Hardware Differences	The XE-pro software was added to the original XE-2100 in order to include additional master programs (IG, RET).	The XT-pro software was added to the original XT-Series in order to include additional master programs (IG, RET).	The XT-Series performs the same as the XE-2100 with the IG and RET masters.
Specimen Type	Random whole blood	Random whole blood	Both systems use the same specimen types.
Throughput	Approximately 113-150 samples/hour depending on the mode used.	Approximately 50-80 samples/hour depending on the mode used.	XT-Series has a lower throughput.
Equivalency Data:	Performance was initially established in XE-2100 510(k) submission (K992875) & then additional masters/parameters were submitted in subsequent submissions: XE-2100 IG (K032039) XE-2100 RET-He (K050589)	Performance of the XT-Series was initially established in 510(k) submission (K021241). The additional IG & RET-He parameters demonstrated excellent correlation.	Data consisting of accuracy, precision and sample stability was collected to show performance to the manufacturer's specification for the IG and RET-He parameters. This analysis supports the claim that the XT-Series IG & RET-He parameters are substantially equivalent to the XE-2100.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 0 2008

Sysmex America, Inc.
c/o Ms. Carrie Pineda
Supervisor, Clinical Affairs
One Nelson C. White Parkway
Mundelein, IL 60060

Re: k081890
Trade/Device Name: IG parameter on Sysmex® XT-Series and RET-He parameters on Sysmex® XT-Series
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: September 25, 2008
Received: September 26, 2008

Dear Ms. Pineda:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding

of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K081890

Device Name: Sysmex® XT-Series, Automated Hematology Analyzer IG & RET-He Parameters

Indications For Use:

The IG parameter on the Sysmex® XT-Series, Automated Hematology Analyzer, is intended for *in vitro* diagnostic use to classify and count immature granulocyte cells in EDTA anti-coagulated blood. The RET-He parameter on the Sysmex® XT-Series, Automated Hematology Analyzer, determines the hemoglobin of reticulocytes for *in vitro* diagnostic use in EDTA anti-coagulated blood.

IG% / #	Immature Granulocyte Percent and Count
RET-He	Reticulocyte Hemoglobin

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Division Sign-Off

Concurrence of CDRH, Office of Device Evaluation (ODE)

Office of In Vitro Diagnostic Device Evaluation and Safety